## IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

| JUNE CHO,                               | )                               |
|---|---------------------------------|
| Plaintiff,                              | )<br>)                          |
| v.                                      | ) Case No. 1:18-cv-00288-WO-JLW |
| DUKE UNIVERSITY and MARILYN HOCKENBERRY | )<br>)<br>)                     |
| Defendants.                             |                                 |
| ·                                       | )                               |

### **DECLARATION OF GEETA SWAMY**

- 1. My name is Geeta Swamy. I am over the age of 18 and am competent to make this Declaration which is based on my own personal knowledge and I give this Declaration as part of the lawsuit brought by June Cho ("Dr. Cho").
- 2. I am currently the Duke University School of Medicine Vice Dean and Associate Vice Provost for Scientific Integrity. Prior to assuming this role in November 2018, I held the position of Associate Dean for Regulatory Oversight & Research Initiatives and served as the Lead IRB Chair.
- 3. The IRB's mission is to ensure the protection of human research subjects through compliance with federal regulatory requirements and institutional policies. All human subject research study protocols must be reviewed and approved by the IRB. Any changes to the protocols as the study progresses must also be submitted and approved prior to implementation. Duke's IRB also reviews potential safety events or protocol deviations to determine whether there has been an infraction, and, if so, a proper course of action.
- 4. Duke's IRB currently has twelve (12) chairs. A chair may review an individual event. Depending on the severity or number of events, a review by the convened IRB may be required. The Duke Medicine IRB has nine separate convened IRBs, eight of which meet monthly. The nine convened IRBs vary in number of primary members and composition, but range from approximately 9 to 16 primary members. IRB members who sit on the boards are drawn from the surrounding Durham community and from various disciplines across Duke to help ensure diverse views

- and backgrounds are represented. IRBs are not unique to Duke. IRBs exist at other institutions conducting human subject research subject to federal regulations.
- In December 2016, the IRB was notified of Dr. Cho's reopening study subject 5. enrollment at the University of Alabama at Birmingham ("UAB") without approval. The IRB was also made aware that the Neonatal-Perinatal Research Unit would no longer support Dr. Cho's study. There were also concerns that proper data transfer agreements may not be in place. In light of these issues, I requested an IRB full board review. Unlike a single incident review, the full board looks at the history of the study. After reviewing the history of the study in its totality, the board unanimously voted to recommend that based on a pattern of non-compliance, Dr. Cho's PI privileges be revoked.
- The IRB submitted its recommendation to the Dean of the School of Medicine who 6. is the Institutional Officer tasked with making a determinations based on IRB recommendations. The Dean at the time was Dr. Nancy Andrews. Dr. Andrews agreed with the IRB's recommendation and informed Dr. Cho that her PI privileges were revoked and reiterated that determination on May 16, 2017. A true and correct copy of correspondence from Dr. Andrews to Dr. Cho on which I was copied is attached hereto as Attachment A.
- Dr. Marilyn Hockenberry was one of the IRB chairs at the time Dr. Cho's study was 7. reviewed. Dr. Hockenberry did not participate in the full board review and played no role in the board's recommendation.

### DECLARATION PURSUANT TO 28 U.S.C. § 1746

I declare under penalty of perjury, pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Geeta Swamy

Date: April 11, 20191

# ATTACHMENTS TO THE DECLARATION OF

## **GEETA SWAMY**

#### June Cho

From:

Nancy Andrews, M.D., Ph.D.

Sent:

Tuesday, May 16, 2017 10:58 AM

To:

June Cho

Cc:

Mark Stacy, M.D.; Geeta Swamy, M.D.; Marion Broome, Ph.D.

Subject:

your letter

Dear Dr. Cho,

I received your letter appealing my earlier decision, based on concurrence with the IRB, to remove you from PI status at Duke.

The IRB recommendation to me listed more issues and more disregard for proper procedures than I remember seeing in any other case over the past decade. In contrast to what you have suggested in your letter, I find it extremely difficult to believe that Dr. Hockenberry or those working with her fabricated the concerns that were raised. The School of Nursing CRU tried to help you get back on course, but you continued to show a lack of willingness or lack of ability to follow proper procedures. The IRB's decision seemed well considered and I have no reason to reject it. As Institutional Official, I cannot support your request to be reinstated as a PI.

Sincerely,

Nancy C. Andrews, M.D., Ph.D.

